UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA ex rel. John King and Tammy Drummond, et al.,	§	
*Plaintiff*s,	§	
v.	§	CIVIL ACTION H-06-2662
SOLVAY S.A., et al.,	§	
Defendants.	§	

ORDER

Pending before the court is a motion for partial summary judgment filed by defendant Solvay Pharmaceuticals, Inc. ("SPI").[1] Dkt. 303. Having considered the motion, response, reply, and applicable law, the court is of the opinion that the motion should be GRANTED IN PART AND DENIED IN PART.

I. BACKGROUND

This is a False Claims Act case. Relators assert that the actions of SPI resulted in false claims being submitted to the government for reimbursement of three SPI drugs: Aceon, Luvox, and AndroGel. While there are many different claims in this case, the instant motion for partial summary judgment relates only to the claims contained in Part VI(C)(ii)(d) of the fifth amended complaint. Dkt. 154. Part VI of the fifth amended complaint is about SPI's alleged scheme to sell Luvox, Aceon, and AndroGel through off-label marketing and illegal kickbacks. *Id.* Part VI(C) addresses, specifically, the allegation that SPI targeted Medicaid and other government health programs, gained

[1] Solvay Pharmaceuticals, Inc. ("SPI") is now known as AbbVie Products, LLC.

formulary access by deceit and other means, and caused claims arising from such tactics and off-label promotions to be submitted for payment. *Id.* Part VI(C)(ii) deals with targeting and wooing doctors based on Medicaid/TRICARE/Medicare volume, and Part VI(C)(ii)(d) is about, specifically, wooing Medicaid Pharmaceutical and Therapeutics Committee ("P&T Committee") Members. *See id.* at 119. This section of the fifth amended complaint alleges that SPI "actively targeted doctors who were members of states' Medicaid [P&T Committees] and pushed its off-label messages for its drugs in an effort to obtain placement of its drugs on state Medicaid formularies." *Id.* Relators allege that the "off-label promotion . . . resulted in scripts filled by pharmacies," which "then submitted such false claims to government health plans . . . ." *Id.* at 110 (Part VI(C)). Relators allege that the claims were not only "tainted by deception, but in many cases the claims were otherwise medically unnecessary or inappropriate." *Id.*

SPI moves for partial summary judgment on Relators' theory that SPI caused submission of false claims to Medicaid from 1997 – 2007 by wooing members of state P&T Committees to obtain preferred status for Aceon, AndroGel, or Luvox on a preferred drug list ("PDL") or Medicaid formulary. Dkt. 304. SPI argues that Relators can only survive summary judgment if they have evidence that the wooing actually resulted in SPI's drugs receiving a preferred listing or being added to a formulary and, if so, that claims for nonreimbursable prescriptions were submitted and paid as a result. *Id.* SPI contends that Relators' theory is based on a misunderstanding of the impact of a PDL listing, and that, in any event, Luvox was never listed on a PDL in any state and only fourteen states listed Aceon or AndroGel during the relevant time period. *Id.* SPI requests, at a minimum, that the court grant summary judgment with regard to this theory for all states and time periods where there is no evidence that the drugs at issue were on a state PDL. *Id.*

Relators argue that if SPI had not disseminated falsehoods about its drugs to state Medicaid agencies to keep its drugs free of administrative controls, such as prior authorization requirements, the controls would have blocked most of the reimbursement claims made in those states.[2] Dkt. 341 at 1. Relators assert that SPI ignores that favorable reimbursement status could be bestowed by groups other than P&T Committees, including a Drug Utilization Review ("DUR") Board, and that these groups can choose to block claims for reimbursement or freely allow claims in numerous way, including not only PDLs, but also formularies and prior authorization systems. *Id.* at 2. They assert that they have always focused on SPI's actions to obtain fewer administrative controls by influencing decisionmakers of all types, including DUR Board members, to obtain preferential status. *Id.* They point out that the fifth amended complaint contains a section that explains the roles of DUR Boards and prior authorization systems, and that SPI's focus on PDLs implemented by P&T Committees is therefore inappropriate. *Id.*

II. LEGAL STANDARD

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Carrizales v. State Farm Lloyds*, 518 F.3d 343, 345 (5th Cir. 2008). The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly

[2] Generally, when a drug is on a mandatory PDL or formulary, physicians do not have to receive prior authorization before prescribing the drug. *See, e.g.*, Dkt. 341, Ex. 258 at 6. "PDLs may b voluntary or mandatory. A voluntary PDL is where a list of preferred medications is developed and communicated to providers but reimbursement of non-preferred medications is not restricted. . . . Under a mandatory PDL program, however, non-preferred medications will only be reimbursed by Medicaid after having been subjected to a prior authorization process . . . an approved. Preferred drugs on the PDL are not subjected to a prior authorization approval process." *Id.* at 6–7.

supported motion for summary judgment; there must be an absence of any genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48, 106 S. Ct. 2505 (1986). An issue is "material" if its resolution could affect the outcome of the action. *Burrell v. Dr. Pepper/Seven Up Bottling Grp., Inc.*, 482 F.3d 408, 411 (5th Cir. 2007). "[A]nd a fact is genuinely in dispute only if a reasonable jury could return a verdict for the non-moving party." *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006).

The moving party bears the initial burden of informing the court of all evidence demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). Only when the moving party has discharged this initial burden does the burden shift to the non-moving party to demonstrate that there is a genuine issue of material fact. *Id.* at 322. If the moving party fails to meet this burden, then it is not entitled to a summary judgment, and no defense to the motion is required. *Id* . "For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Transamerica Ins. Co. v. Avenell* , 66 F.3d 715, 718–19 (5th Cir. 1995); *see also Celotex*, 477 U.S. at 323–25. To prevent summary judgment, "the non-moving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (quoting Fed. R. Civ. P. 56(e)).

When considering a motion for summary judgment, the court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant. *Envl. Conservation Org. v. City of Dallas, Tex.*, 529 F.3d 519, 524 (5th Cir. 2008). The

court must review all of the evidence in the record, but make no credibility determinations or weigh any evidence; disregard all evidence favorable to the moving party that the jury is not required to believe; and give credence to the evidence favoring the non-moving party as well as to the evidence supporting the moving party that is uncontradicted and unimpeached. *Moore v. Willis Ind. Sch. Dist.*, 233 F.3d 871, 874 (5th Cir. 2000). However, the non-movant cannot avoid summary judgment simply by presenting "conclusory allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation." *TIG Ins. Co. v. Sedgwick James of Wash.*, 276 F.3d 754, 759 (5th Cir. 2002); *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). By the same token, the moving party will not meet its burden of proof based on conclusory "bald assertions of ultimate facts." *Gossett v. Du-Ra-Kel Corp.*, 569 F.2d 869, 872 (5th Cir. 1978); *see also Galindo v. Precision Am. Corp.*, 754 F.2d 1212, 1221 (5th Cir. 1985).

III. Unopposed Portion of Motion

Relators are no longer asserting a claim that SPI improperly wooed P&T members into including its drugs on the state PDLs or formularies for the following drugs in the listed states:

> (1) **Luvox:** Arizona and Nevada;
> (2) **Aceon:** Alaska, Arizona, Colorado, DC, Indiana, Maine, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Ohio, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Washington, and Wyoming;
> (3) **Androgel:** Arizona, Alaska, Georgia, Idaho, Illinois, Iowa, Maine, Massachusetts, Montana, Nevada, New Hampshire, New Mexico, North Dakota, South Dakota, Vermont, and Wyoming.

SPI's motion for summary judgment with regard to these drugs in these states is GRANTED and the claims are DISMISSED WITH PREJUDICE.

IV. Pleaded Claims

SPI argues that the claims in Relators' complaint are limited to improper influence of P&T Committee members, so any arguments relating DUR Boards and prior authorization requirements not affiliated with a PDL or formulary are outside of the complaint. Dkt. 304 at 31. SPI points out that the deadline to amend the complaint passed two years ago, and inserting arguments about an unpleaded theory at this point is improper. *Id.* Relators argue that the fifth amended complaint indicates that decisions about PDLs or formularies are made by P&T Committees *or* Drug Utilization Review ("DUR") Boards. Dkt. 341; *see* Dkt. 154 ¶ 41 (fifth amended complaint). Thus, Relators urge the court to allow evidence of drugs being placed on a PDL or formulary or being left off of a prior authorization list by a P&T Committee *or* a DUR Board as evidence supporting their claim about "wooing P&T Committee members." Dkt. 341.

A. P&T Committee Members Versus DUR Boards

The court has thoroughly reviewed the portions of the fifth amended complaint that Relators assert support this broad theory, and the facts Relators have pleaded support only the theory that SPI wooed *P&T Committee* members. While certainly Relators discussed DUR Boards in the general background section of the fifth amended complaint, the portion about "wooing" does not include any discussion of DUR Boards and, in fact, specifically discusses "P&T Committee members" multiple times (including in the title of the section).[3] *See* Dkt. 154 ¶¶ 287–95 ("Wooing Medicaid P&T Committee members" section of the fifth amended complaint). If the State did not have a P&T

[3] The court understands that in some states the DUR Board serves the same function as a P&T Committee. *See, e.g.*, Dkt. 346, Ex. 258 (Medicaid Pharmacy Program Report, State of Nebraska) ("Some states use their current Drug Utilization Review (DUR) Committee to fulfill the responsibilities of the P&T Committee."). Regardless, the fifth amended complaint only refers to the wooing of P&T Committee members.

Committee, then SPI could not have wooed the P&T Committee members to gain preferred status for its drugs. Relators have had five chances and many years to amend their complaint. They were required to plead with particularity, identifying "the who, what, when, where, and how of the events at issue," and the current version of the complaint does not contain particularized allegations relating to the wooing of DUR Board members. *See Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009) (discussing the pleading standard for a False Claims Act case). The inferential leap between P&T Committee members and DUR Board members that Relators urge the court to make is not appropriate in a False Claims Act case. Accordingly, if a state did not have a P&T Committee during the relevant time period, then no allegations that false claims were made as a result of SPI wooing decisionmakers to gain preferential treatment with regard to that state can stand.

B. Formularies Versus PDLs

The fifth amended complaint asserts that SPI "actively targeted doctors who were members of states' Medicaid pharmaceutical and therapeutics ("P&T") committees and pushed its off-label messages for its drugs in an effort to obtain placement of its drugs on the state Medicaid formularies." Dkt. 154 ¶ 287. Throughout the section about wooing P&T committee members, Relators refer to "preferred lists," "preferred status," and "formularies." *Id.* ¶¶ 287–301. SPI contends that no state has successfully used its P&T Committee to establish a Medicaid formulary. Dkt. 304. In so stating, SPI is referring to a specific type of formulary authorized under 42 U.S.C. § 1396r-8(d)(4). *See id.* at 24. SPI argues that because there are no statutorily authorized Medicaid formularies, there is no genuine issue of material fact as to whether SPI caused false claims to be submitted by wooing P&T Committee members to include particular drugs on a Medicaid formulary. *Id.*

Relators argue that the term "formulary" is a generic term used by the states *and* SPI's own employees to refer to lists states use to control conditions of drug reimbursement. Dkt. 341 at 7–8. Indeed, SPI has historically referred to various lists that the states create with regard to access to drugs under Medicaid as "formularies." *See, e.g.*, Dkt. 341, Exs. 193, 289, 298, 299. The reference to "formulary" is thus sufficient to put SPI on notice that Relators are alleging that SPI wooed P&T Committee members to get the drugs at issue on some sort of list that would facilitate access to the drugs at issue by Medicaid patients in some way. The pleading is not, however, sufficient notice of a theory that SPI wooed P&T Committee members to keep the drugs *off* of a prior authorization list, as keeping the drugs off a list is distinct from including them on a "formulary. Thus, the wooing claim is available, pursuant to the pleaded claims in the fifth amended complaint, for states that had a PDL or some type of formulary governed by a group called a P&T Committee during the relevant timeframe if the drugs at issue were on the list. If a state merely kept the drugs at issue *off* of a prior authorization list without having a corresponding formulary or PDL upon which the drugs at issue were placed, the wooing claim is not available.

V. PDLs

SPI asserts several different arguments with regard to specific states that either did or did not have PDLs during the relevant time period. SPI argues that seven states did not have PDLs during the relevant time period and that any claims relating to wooing P&T committee members with regard to these states should be dismissed. The seven states without PDLs are Colorado, Nebraska, New Jersey, North Carolina, Oklahoma, North Dakota, and South Dakota.[4] Dkt. 304. SPI asserts that for

[4] As noted in Part III, *supra*, Relators have already agreed to dismiss their claims with regard to some of these drugs in some of these states. Relators still assert claims for Luvox and AndroGel in Colorado and Nebraska, all three drugs in New Jersey, North Carolina, and Oklahoma, and Luvox

twenty-four states and the District of Columbia, the available records show that none of the three drugs at issue were on the state PDLs.[5] Dkt. 304 at 28 (listing the 24 states). SPI argues that Relators thus could have no evidence that any improper wooing caused the drugs to be listed on a PDL. *Id.* SPI asserts that there are only eight states in which there is evidence that AndroGel was on a state PDL during the relevant time period—Delaware, Florida, Louisiana, Maryland, Pennsylvania, Texas, West Virginia, and Wisconsin—and only eleven states where there is evidence that Aceon was on the PDL during the relevant time period—Alabama, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Louisiana, Maryland, South Carolina, and West Virginia. Dkt. 304 at 28. Luvox was not preferred on any of the states' PDLs. *Id.* at 11. SPI thus requests summary judgment for all states and time periods when the drugs at issue were not on PDLs. *Id.*

Finally SPI argues that eight states no longer have records indicating what drugs were on their PDLs during the relevant time period: Arkansas, Indiana, Kansas, Minnesota, New Mexico, Rhode Island, Washington, and Wyoming. Dkt. 304 at 29. SPI requests summary judgment on Relators' claims for these states, arguing that the absence of evidence showing that SPI's drugs were on the PDLs is fatal to Relators' theory that SPI improperly influenced these states to include the drugs on their PDLs. *Id.*

SPI focused its briefing on whether the states had a means of administrative control called a "PDL," which is too narrow since the fifth amended complaint uses the generic term "formulary." Relators focused their briefing on whether the states had *any* type of administrative control over the

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in North Dakota and South Dakota.

[5] These states are: Alaska, California, Georgia, Hawaii, Indiana, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, New Hampshire, New York, Ohio, Oregon, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Dkt. 304 at 28.

drugs (including prior authorization requirements) implemented by a P&T Committee *or* a DUR Board, which is too broad since the fifth amended complaint specifically delineates "P&T Committee members." If the states that had P&T Committees had a means of administrative control of these drugs that could be considered a formulary *or* PDL, and the drugs at issue were on the formulary or PDL during the relevant time, that is enough to prevent summary judgment *at this stage*, as SPI is simply seeking partial summary judgment for states that did not even list the drugs at issue during the relevant time period.

Of all of these states, the court has ascertained from the current record that the following states had a P&T Committee at some point during the relevant time period: Florida, Idaho, Illinois, Kansas, Kentucky, Louisiana, Ohio, Oregon, South Carolina, Texas, and West Virginia. See Exs. 116–17, 123, 130–31, 180–81, 187, 191–93, 241, 323 (Florida); Ex. 196 (Idaho); Ex. 289 (Illinois); Ex. 270 (Kansas); Exs. 174, 348 (Kentucky); Exs. 6–7, 15, 109–11, 142, 275, 278, 350–54 (Louisiana); Exs. 3, 209, 216–18, 300 (Ohio); Ex. 267 (Oregon); Exs. 18–19, 97, 101, 259 (South Carolina); Exs, 203–07 (Texas); and Exs. 20, 314 (West Virginia).[6] While certainly some of these states also had PDLs at some point, and SPI provides evidence that the drugs at issue were not on the PDLs during some of the time listed, it is unclear whether any of the states with P&T Committees had any other type of formulary managed by a P&T Committee that listed the drugs at issue during the relevant time period. It would be inappropriate to grant summary judgment based solely on the fact the drugs were not a PDL when they could have been, at some point, on a formulary managed by a P&T Committee. Since neither party addressed this point in the briefing,

[6] The court recognizes that other states may have had P&T Committees as well, but could not find reference to such committees in the current record.

the court finds that summary judgment is unwarranted on the current record. SPI's motion for summary judgment on these grounds is thus DENIED WITHOUT PREJUDICE.[7]

VI. Reimbursability for Off-Label Uses

SPI argues that even when the drugs at issue were on a PDL, it did not render the claims for reimbursement of prescriptions of the drugs false. Dkt. 304 at 24. SPI notes that PDL listings only determine whether a drug is subject to a prior authorization requirement and that the Medicaid statute mandates that all drugs, whether preferred or not, must be covered for medically accepted indications. *Id.* Thus, failure to list a drug on a PDL does not exclude the drug from coverage or expand the medically indicated uses. *Id.* at 25. Relators argue that preferred placement on a PDL does lead to false claims because if the drugs had been subject to prior authorization or other administrative controls that the PDL dispenses with, most improper reimbursement claims would have been blocked. Dkt. 341 at 5. While the court agrees that simply being on a PDL does not render the claims for reimbursement of the drug false and agrees that many of the prescriptions for drugs listed on PDLs are likely not false claims, the court also agrees with Relators that placement on PDLs could lead to more false claims. Relators provide some evidence that utilization increases when drugs are on a PDL or formulary. *See* Dkt. 341, Apps. B, C, D. Thus, to the extent SPI seeks summary judgment on this claim merely because the claims for drugs listed on PDLs are not automatically rendered false claims, the motion is DENIED.

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[7] SPI may file a supplemental motion for summary judgment on these grounds now that it has the benefit of the court's interpretation of the pleaded claims. However, the court strongly encourages the parties to meet and confer diligently prior to SPI filing another motion, as certainly given the guidance in this order there should be agreement as to which states do not fit within the pleaded theory.

VII. Conclusion

SPI's motion for partial summary judgment (Dkt. 303) is GRANTED IN PART AND DENIED IN PART. SPI's motion with regard to the drugs and states listed in Part III is GRANTED, and those claims are DISMISSED WITH PREJUDICE. SPI's motion on the grounds that certain states did not have PDLs, that the drugs at issue were not on the PDLs, or that PDLs are unavailable is DENIED WITHOUT PREJUDICE to reassert now that the court has clarified the extent of the pleaded claims. SPI's motion for summary judgment on the ground that claims are not rendered false simply because the drugs were on a PDL is DENIED.

Signed at Houston, Texas on January 23, 2015.

Gray H. Miller
United States District Judge